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10/786,789

02/25/2004

Colin P. Hart

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/786,789	<b>Applicant(s)</b> HART ET AL.	
	<b>Examiner</b> CHRISTOPHER D. KOHARSKI	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 20-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/24/2004</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 14-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group (Group I selected, claims 1-13 and 20-32), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/21/2007.

### ***Response to Amendment***

Examiner acknowledges the reply filed 12/21/2007 in which claims 1-32 are pending for examination with claims 14-19 are withdrawn from an election restriction.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) that was submitted on 5/24/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 20-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,699,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the current pending application are anticipated by the claims in the cited US patent.

**Application claim 1 requires:**

A fluid injection apparatus adapted to inject fluid, comprising: an input device; a catheter in fluid communication with the input device; and an improved visualization device operatively associated with one of the input device and catheter and adapted to increase the speed with which fluid may be injected.

**While patent claim 1 requires:**

An angiography device, comprising: a catheter inserted into a blood vessel; a source of radiopaque fluid; an injector fluidically connected to the source of radiopaque fluid and the catheter, the injector driving the radiopaque fluid from the source to the catheter and into the blood vessel; a heater heating the radiopaque fluid, the heater reducing the viscosity of the radiopaque fluid thus increasing the speed with which the radiopaque fluid is introduced into the blood vessel; and an expandable ring provided on the catheter, the expandable ring constricting blood flow through the blood vessel when expanded thus decreasing the speed with which the radiopaque fluid is

diluted in the blood vessel.

### ***Specification***

The abstract of the disclosure is objected to because it exceeds the 150 word maximum. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: The priority paragraph needs to be updated with the proper prior application information.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-5, 20 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 1 and 4-5, Examiner asserts that the "visualization device" is indefinite; it is unclear that how a heater and expandable ring are considered a "visualization device." Regarding claims 20 and 24, Examiner asserts that the "...a catheter connected to the second end of the catheter..." is unclear and indefinite; the second catheter referenced has no antecedent basis and only one catheter is claimed, it is unclear how it can be connected to itself.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-10, 12, 20-22, 27-29, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans, III et al. (USPN5,885,216). Evans, III et al. discloses a total system for contrast delivery.

Regarding claims 1-4, 6-10, 12, 20-22, 27-29, and 31, Evans, III et al. discloses a manually operated fluid injection system (Figure 1), comprising: a syringe (31) having a movable plunger; a manifold (near 20) having a plurality of input ports and first and second ends, the syringe (31) being connected to the first end of the manifold; a series of valves for fluid flow (12, 13, 21, and 25); a fluid line (connection between elements 14-26) having first and second ends, the first end of the fluid line being connected to one of the plurality of input ports; a source of contrast fluid (col 4, ln 20-40) in communication (10, 11) with the fluid line; and a heater (14, 15) operatively associated with one of the syringe (31), manifold (near 20), fluid line, catheter (27) and source of fluid (Figures 1-2).

### ***Claim Rejections - 35 USC § 102***

Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Cragg (USPN5,085,635). Cragg discloses a valve-tip angiographic catheter.

Regarding claim 32, Cragg discloses a manually operated fluid injection system, comprising: a manipulable input device (18); a catheter (10) connected to the input device; an expandable member (28) associated with the catheter and adapted to expand after the catheter is inserted into a patient to restrict blood flow during injection (Figure 4).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C 103(a) as being unpatentable over Evans, III et al. (USPN5,885,216) in view of Cragg (USPN5,085,635). Evans, III et al. meets the claim limitations as described above except for an expandable member proximate a distal end of the catheter.

However, Cragg teaches a valved-tip angiographic catheter.

Regarding claim 5, Cragg teaches a manually operated fluid injection system, comprising: a manipulable input device (18); a catheter (10) connected to the input device; an expandable member (28) associated with the catheter and adapted to expand after the catheter is inserted into a patient to restrict blood flow during injection (Figure 4).

At the time of the invention, it would have been obvious to add the expandable element to the system of Evans, III et al. in order to control the flow of the contrast agent and minimize backflow in the blood vessel. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Cragg (cols 1-2).

***Claim Rejections - 35 USC § 103***

Claims 11, 13, 23 and 30 are rejected under 35 U.S.C 103(a) as being unpatentable over Evans, III et al. (USPN5,885,216) in view of Kistner et al. (USPN6,139,528). Evans, III et al. meets the claim limitations as described above except for an integrated manifold coil heater assembly.

However, Kistner et al. teaches an intravenous warming system.

Regarding claims 11, 13, 23 and 30, Kistner et al. teaches an intravenous warming system (Figure 1B) in which a catheter (32) with needle assembly (30) allows for a fluid source (12) to be electrically heated via a coil manifold (10) assembly (Figures 1-2).

At the time of the invention, it would have been obvious to integrate the heating assembly of an inline heater to the system of Evans, III et al. in order to reduce the need for a pre-heating bulk heating assembly. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Kristner et al. (cols 1-2).



***Claim Rejections - 35 USC § 103***

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woelpper et al. (USPN5,569,208) in view of Cragg (USPN5,085,635).

Regarding claims 24-26, Woelpper et al. discloses a manually operated fluid injection system (Figure 2), comprising: a syringe (58') having a movable plunger (60'); a manifold (50') having a plurality of input ports and first and second ends, the syringe (58') being connected to the first end of the manifold; a series of valves for fluid flow (34', 70', and 72'); a fluid line (46') having first and second ends, the first end of the fluid line being connected to one of the plurality of input ports; a source of contrast fluid (20') in communication (46') with the fluid line (Figures 1-8).

Woelpper et al. meets the claim limitations as described above except for an expandable member proximate a distal end of the catheter.

However, Cragg teaches a valved-tip angiographic catheter.

Regarding claims 24-26, Cragg teaches a manually operated fluid injection system, comprising: a manipulable input device (18); a catheter (10) connected to the input device; an expandable member (28) associated with the catheter and adapted to expand after the catheter is inserted into a patient to restrict blood flow during injection (Figure 4).

At the time of the invention, it would have been obvious to add the expandable element to the system of Woelpper et al. in order to control the flow of the contrast agent and minimize backflow in the blood vessel. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one

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skilled in the art would have combined the teachings in the references in light of the disclosure of Cragg (cols 1-2).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 3/10/2008

/Christopher D Koharski/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

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